510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

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FEB - 7 2011

Date Prepared: August 30, 2010

B. Device Name

Trade or Proprietary Name:	*NuVasive® CoRoent® Small Interlock™ System*
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device
Device Class:	Class II
Classification:	§888.3080
Product Code:	ODP

C. Predicate Devices

The subject *CoRoent Small Interlock System* is substantially equivalent to the following devices previously cleared by FDA:

- K072415 – Surgicraft Limited STALIF™ C
- K072981– Synthes Spine Synthes Zero-P
- K083389 – Globus Medical Coalition™ Spacer
- K094042– Medtronic Sofamor Danek PEEK PREVAIL™ Cervical Interbody Device
- K092521– SeaSpine, Inc. Zuma-C™
- K100043– NuVasive, Inc. CoRoent XLR Standalone System

D. Device Description

The NuVasive *CoRoent Small Interlock System* is a standalone anterior cervical interbody device consisting of a PEEK (polyetheretherkeytone) implant cage with titanium alloy radiographic markers and washers, and three (3) titanium alloy bone fixation screws. The devices are manufactured from PEEK-Optima® LT-1 conforming to ASTM F2026 and titanium alloy conforming to ASTM F136. The implants are available in a variety of sizes to accommodate anatomical conditions. The *CoRoent Small Interlock System* is a standalone system intended to be used with the bone screws provided, and when used as such requires no additional supplementary fixation systems.

E. Intended Use

The CoRoent® Small Interlock System is a stand-alone anterior cervical interbody fusion system indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one level from C2-T1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the CoRoent Small Interlock System. The CoRoent Small Interlock System is intended for use with autograft.

F. Technological Characteristics

As was established in this submission, the subject *CoRoent Small Interlock System* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function, and range of sizes.

G. Performance Data

Nonclinical testing and engineering analysis were performed to demonstrate that the subject *CoRoent Small Interlock System* is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic torsion per ASTM F2077
- Static and dynamic compression per ASTM F2077
- Subsidence per ASTM F2267
- Wear Debris per ASTM F2077 & ASTM F1877

The results of these studies showed that the subject *CoRoent Small Interlock System* meets or exceeds the performance of the predicate device, and the device was therefore found to be substantially equivalent.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *CoRoent Small Interlock System* has been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NuVasive, Inc.
% Ms. Sheila Bruschi
Associate Manager, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

SEP

Re: K102547
Trade/Device Name: NuVasive® CoRoent® Small Interlock™ System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: January 10, 2011
Received: January 11, 2011

Dear Ms. Bruschi:

This letter corrects our substantially equivalent letter of February 7, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102547

Indications for Use

510(k) Number (if known): K102547

Device Name: NuVasive® CoRoent® Small Interlock™ System

Indications For Use:

The *CoRoent® Small Interlock™ System* is a stand-alone anterior cervical interbody fusion system indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one level from C2-T1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the CoRoent Small Interlock System. The CoRoent Small Interlock System is intended for use with autograft.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102547